

REMARKS

The Office Action mailed February 25, 2005, has been carefully reviewed. The claims in the application are now claims 2-6, 8-15 and 25-30, and these claims define patentable subject matter and should be allowed. The applicants therefore again respectfully request favorable reconsideration and allowance.

New claims 25-30 have been added. New claims 25-29 are patentable because they depend from and incorporate the subject matter of the claims from which they depend, which are patentable for the reasons given below. New claim 30 is a new independent claim, and it also is patentable for the reasons given below in response to the rejections of record.

The previous rejection based on the first paragraph under Section 112 has been withdrawn. However, claims 2-6, 8-15, 20 and 21 have been newly rejected under the first paragraph of Section 112 "as failing to comply with the written description requirement." This rejection is respectfully traversed.

The issue in the present case has been and apparently continues to be through to the present rejection how to claim the present invention in a way which meets the examiner's requirements, while maintaining the same scope of

claims. Applicants' invention has not changed, and applicants have no reason to narrow the scope of their claims, as the prior art (discussed below) simply does not come anywhere near the present invention.

Consequently, applicants have substantially amended claims 6 and 8 with a view to addressing the points raised in the rejection. The Jepson form has been adopted for these claims in order to focus the novel and unobvious aspects of the present invention in the improvement clauses. However, applicants wish to be very express and clear on the point that applicants do **not** admit that anything appearing in the preamble of the Jepson claims is admitted to be prior art, and therefore the Jepson preambles are not to be taken as admissions by applicants in the present case. In particular, the Jepson preambles are not to be taken as any admission that plural markers have been used together in the prior art for any testing purpose even remotely related to the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 2-6, 8-17, 20 and 21 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

The amendments presented above are believed to obviate this rejection. Applicants respectfully repeat the comments made above in reply to the rejection based on the first paragraph of Section 112.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 2-6 have been rejected as anticipated by Koizumi et al, Reference V ("Koizumi"). This rejection is respectfully traversed.

Koizumi discloses the use of a single tumor marker for diagnosing bone metastasis in patients with cancer. This is the very type of prior art over which the present invention provides an improvement, it being noted that the use of plural markers is absolutely essential to the present invention. Thus, the present invention clearly defines novel subject matter over Koizumi in that the present invention is characterized by (1) the combination of markers, and (2) the determination of Z values and the use of a crossover index, subject matter totally absent from Koizumi

Withdrawal of the rejection is in order and is respectfully requested.

Claims 8-15 have been rejected under Section 102 as anticipated by Martinetti et al, Reference U ("Martinetti"). This rejection is respectfully traversed.

Martinetti also (like Koizumi) does not disclose applicants' claimed subject matter. Martinetti discloses the use of a single tumor marker for evaluating osteoblastic and osteoclastic markers with bone metastasis, and treated with formestane. In contrast to Martinetti, the present invention is characterized by (1) the use of a **combination** of markers, and (2) the determination of Z values and the use of a crossover index. As is the situation with Koizumi, Martinetti does not disclose the combination of (1) and (2), and thus claims 8-15 are not anticipated by Martinetti.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art has not been applied under Section 103, and applicants agree that neither Koizumi nor Martinetti teach any subject matter which would lead the person of ordinary skill in the art to or toward the present invention. There are no teachings of how to modify either of these references to even begin to reach applicants' claims.

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Applicants believe that all issues raised in the  
Official Action have been addressed in a manner favoring  
patentability.

Applicants accordingly respectfully request  
favorable reconsideration and allowance.

Respectfully submitted,

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